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EXAMINER	
SHTERENGARTS, SAMANTHA L	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/591,722	SAITOU ET AL.	
	Examiner	Art Unit	
	Samantha L. Shterengarts	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *16-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/26/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. The instant application is a national stage entry of PCT/JP05/04189, filed March 10, 2005.

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interfering reference, a certified English translation of the foreign application must be submitted in reply to this action. 37 CFR 41.154(b) and 41.202(e).

Failure to provide a certified translation may result in no benefit being accorded for the non-English application. (See 102(a) rejection below.)

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on September 26, 2007 was in compliance with the provisions of 37 CFR 1.97 and 37 CFR 1.98. The IDS document was considered. A signed copy of form 1449 is enclosed herewith.

Election/Restrictions

4. Applicant's election with traverse of Group I in the reply filed on June 12, 2009 is acknowledged. The traversal is on the ground(s) that 37 C.F.R. 1,475 provides that unity of invention will be considered if claims are drawn only to one of the following combinations of categories from (1) thru (5) and further that the restriction requirement does not clearly set forth why unity is lacking regarding the special technical feature. Also, the election of species

requirement is traversed because Examiner must establish that the claims lack unity of invention. This is not found persuasive for the following reasons.

An international application should relate to only one invention or, if there is more than one invention, the inclusion of those inventions in one international application is only permitted if all inventions are so linked as to form a single general inventive concept (PCT Rule 13.1). With respect to a group of inventions claimed in an international application, unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features.

The claims herein lack unity of invention under PCT rule 13.1 and 13.2 since, under 37 CFR 1.475(a)

Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The groups lack unity of invention since under 37 CFR 1.475: the technical feature corresponding to the claims is the compounds of formula 1. This special technical feature is not a special technical feature because it fails to define a contribution over the prior art as can be seen in Yamazaki et al. (WO 04/024697), which discloses the same core as in formula 1.

Therefore, claims 1-19 are not so linked as to form a single general inventive concept and there is a lack of unity of invention because they lack a special technical feature as the technical feature present fails to define a contribution over the prior art. The core technical feature that is

being claimed is taught by the prior art. Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper.

Furthermore, even if unity of invention under 37 CFR 1.475(a) is not considered lacking, which it is as evidenced above, unity is lacking under 37 CFR 1.475(b). Under 37 CFR 1.475(b): A national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations:

(1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and a process of use of said product; or

(3) A product, a process specially adapted for the manufacture of said product, and a use of said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of said product, and an apparatus or means specifically designed for carrying out the said process.

And according to 37 CFR 1.475(c): if an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph 37 CFR 1.475(b), unity of invention might not be present.

Therefore, since the claims are drawn to compounds and compositions, which do not make a contribution over the prior art, as well as *various* methods of using the compounds of formula 1 (claims 16-19) and according to 37 CFR 1.475(e): the determination whether a group

of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claims.

Therefore, since the claims do not relate to a single general inventive concept under PCT Rule 13.1 and lack the same or corresponding special technical feature, the claims lack unity of invention.

The requirement is still deemed proper and is therefore made FINAL.

5. According to MPEP 803.02, the election of species is found free of the art and therefore, the search of the Markush claims will be extended. The search is extended to include all products of formula 1.

6. Claims 1-15 are under consideration. Claims 16-19 are withdrawn for being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

(First Paragraph)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

As stated in the MPEP 2164.01(a), "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue."

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have need described. They are:

1. The nature of the invention
2. The state of the prior art
3. The predictability or lack thereof in the art
4. The amount of direction or guidance present
5. The presence or absence of working examples
6. The breadth of the claims
7. The quantity of experimentation needed, and
8. The level of skill in the art

7. Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compounds of the Formula (1) and pharmacologically acceptable salts thereof, does not reasonably provide enablement for prodrugs thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and, concomitantly, to use the invention commensurate in scope with these claims.

The Nature of the Invention

The instant invention is drawn to a compound of the Formula (1), pharmacologically acceptable salts thereof, and prodrugs thereof. Finding a prodrug is an empirical exercise. Predicting, e.g., if a certain compound is in fact a prodrug that produces the active compound metabolically at a therapeutic concentration and a useful rate, is filled with experimental uncertainty. Attempts have been made to predict drug metabolism *de novo,* but this is still an experimental science. A prodrug of a compound must meet three tests. It must itself be biologically active. It must be metabolized to a second substance *in vivo* at a rate and to an extent

to produce that second substance at a physiologically meaningful concentration. Thirdly, that second substance must be biologically active. Determining whether a particular compound meets these three criteria requires a clinical trial setting and a large quantity of experimentation.

The State of the Prior Art

"Pro-drugs" are commonly known in the art as drugs which are administered in an inactive (or less active) form, and then metabolized in vivo into an active metabolite. As disclosed in Stella (Expert Opinions *Prodrugs as therapeutics*), "prodrugs are bioreversible derivatives of drug molecules used to overcome some barriers to the utility of the parent drug molecule. These barriers include, but are not limited to, solubility, permeability, stability, presystemic metabolism, and targeting limitations" (277). Stella, Valentino J, Expert Opinion of Therapeutic Patents, *Prodrugs as therapeutics*, 2004 14(3): 277-280. Wolff et al. (Burger's Medicinal Chemistry, 5th Ed., Vol. 1, pgs. 975-977, 1994) summarizes that state of the prodrug art, the lengthy research involved in successfully identifying a prodrug, and difficulties of extrapolating between species. With the limited direction and exemplification the specification offers, it is highly unpredictable that the compounds of the Formula (I) will actually form effective prodrugs. Testa, Bernard, Biochemical Pharmacology, *Prodrug Research: futile or fertile?* 68 (2004) 2097-2106, discloses, on page 2098, the various challenges in prodrug research, concluding that all of these challenges may render prodrug optimization difficult to predict and achieve. Finally, Ettmayer, Peter, Medicinal Chemistry, *Lessons Learned from Marketed and Investigational Prodrugs,* 47(10) (2004) 2394-2404, discloses, on page 2401, that "the prodrug strategy should only be considered as a last resort to improve the oral bioavailability of important therapeutic agents" and "At the beginning of each prodrug program,

there should be a clear definition of the problem to solve and defect to improve. The prodrug approach should not be misunderstood as a universal solution to all barriers to a drug's usefulness, and on page 2402, "The majority of all prodrug approaches face the challenge of identifying the optimal prodrug plus its activation system to enhance or prolong the concentration of the active principle at the site of action. Because of the complex situation of prodrug transport and processing, we recommend, especially for novel prodrug principles, that the first step should be to design and investigate different prodrug prototypes of high diversity (different attachment sites, linkers, promoieties, hydrolytic, oxidative, reductive activation, chemical vs. enzymatic activation)." Ettmayer et al. concludes that "the focus on victorious prodrugs should not be misunderstood as neglecting the inherent difficulties and additional layers of complexity a prodrug strategy might face." The evidence supports the conclusion that the method of making claimed prodrugs is a subject for further study and experimentation.

The Level of Skill in the Art and the Predictability or lack thereof in the art

The level of skill of the pharmacological art involves screening in vitro and in vivo to determine which compounds exhibit the desired pharmacological activities as prodrugs. There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any prodrug on its face, without evidence to support that particular prodrug. It is noted that the pharmaceutical art is unpredictable and requires the embodiments to be individually assessed for physiological activity. Thus, the more unpredictable the art, the more information in support of the invention is required to satisfy the statute. See *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970). Various embodiments of

the divergent group of prodrugs claimed herein must be supported by this invention in order to be enabled for the full range of prodrugs of compounds of the Formula (1).

The Amount of Direction or Guidance Present

Prodrugs are defined in the specification as "[0076] the prodrug is a precursor substance that becomes an effective drug through chemical or biochemical metabolism after administration to the living body. Specifically, the prodrug is a compound which is obtained by binding one or more appropriate groups, that is eliminated by metabolism in the living body, such as alkoxycarbonyl group or dialkylaminosulfone group with N in the ring or chain of a heterocycle or the like contained in the compound represented by the general formula (1). Alternatively, the prodrug is a compound coupled with one or more ester groups, amide groups, or the like that utilize alcohol or carboxylic acid, which may be contained in the compound represented by the general formula (1)." This disclosure is directed to any pharmaceutically acceptable prodrug; however, as discussed above, it would be necessary for Applicant to provide evidentiary support for exemplary embodiments due to the unpredictability in the art with regards to the success of prodrugs with some drugs over others. There are no working examples in the specification that show how to make or use any prodrugs of the instantly claimed compounds. Additionally, the lack of working examples in the specification is not sufficient to enable one skilled in the art to which it pertains to make and use any pharmaceutically acceptable prodrug as interpreted broadly by one of ordinary skill in the art. The specification does not adequately enable a method of making prodrugs of the compounds that the claims encompass, as defined in the instant specification. The specification has limited exemplification thereof and of the necessary starting materials, as discussed *supra*.

As stated in Morton International Inc. v. Cardinal Chem, Co., 28 USPQ2d 1190:

> [T]he specification purports to each, with over fifty examples, the preparation of the claimed compounds with the required connectivity. However... there is no evidence that such compounds exist... the examples of the patent do not produce the postulated compounds..., there is...no evidence that such compounds even exist.

The same circumstance is true here.

The Breadth of the Claims

The claims are drawn to any compound which is converted to a therapeutically active compound after administration, and the term should be interpreted as broadly in the instant application as is generally understood in the art. As discussed above, this broad disclosure cannot possibly enable one skilled in the art to which it pertains to make and use any pharmaceutically acceptable prodrug due to the unpredictability in the art with regards to the success of prodrugs with some drugs over others.

The specification provides limited support, as noted above, for the large number of prodrugs encompassed by the claims. The quantity of experimentation needed to make and use all of the prodrugs encompassed by the claims would be an undue burden on one skilled in the chemical art, since the skilled artisan is given inadequate guidance for the reasons state above. Even with the undue burden of experimentation, there is no guarantee that one would obtain the desired prodrugs in view of the Wolff reference.

The Quantity of Experimentation Needed

Based on the unpredictable nature of the invention and the state of the prior art and the breadth of the claims, one of ordinary skill in the pertinent art would be burdened with undue experimentation study to determine whether any pharmaceutically acceptable prodrug of

compounds of the Formula (1) would successfully act as prodrugs as they are known in the art. Therefore, in view of the Wands factors discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test which prodrugs, if any, would produce desired activity with compounds of the Formula (1) with no assurance of success.

8. Claims 1-15 are rejected under 35 U.S.C. 112 1st paragraph as failing to comply with the written description requirement.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor has possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); In re Gostelli, 872 F.2d 10081 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In Regents of the University of California v. Eli Lilly & Co. the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those

specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") *Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.*

The MPEP states that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP § 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad genus. In *Gostelli*, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The Guidelines for Examination of Patent Applications Under 35 USC 112, ¶1, "Written Description" Requirement (Federal Register, Vol. 66, No. 4, pg. 1105, column 3), in accordance with MPEP § 2163, specifically state that for each claim drawn to a genus the written description requirement may be satisfied through sufficient description of a representative number of species by a) actual reduction to practice; b) reduction to drawings or structural chemical formulas; c) disclosure of relevant, identifying characteristics (i.e. structure) by functional characteristics coupled with a known or disclosed correlation between function and structure. The analysis of whether the specification complies with the written description requirement calls for the examiner to compare the scope of the claim with the scope of the description to determine whether applicant has demonstrated possession of the claimed invention (Federal Register, Vol. 66, No. 4, p. 1105, 3rd column, 3rd paragraph). Below is such a comparison.

I. ***Scope of Claims***

Compounds of the formula 1:

The variables A_1, A_2, R_1, R_2, R_3, R_4, R_5, R_6, W, X, D (Q, Y, B), R_{18}, R_{19}, R_{20}, R_{21}, R_{22}, R_{23}, Z, are claimed *broader* than what is supported by the disclosure (see section II below).

II. ***Scope of Disclosure***

Reduction to Practice:

The compounds reduced to practice support the following substituents for the aforementioned variables:

A_1: imidazole substituted with $-S(O)_2$-Me or $-CH_2$-COOH

A_2: imidazole

R_1, R_2, R_3, R_4, R_5, R_6: hydrogen

W: benzene ring, all groups represented by formulae (10) and (11), substitutable only by alkyl or C=O

X: CH_2, $R_{31}N$-C=T_5-NR_{32}, C=O

D: Q—Y—B

Q: single bond, NR_{12}

Y: formula (7), alkylene of any length

R_{18}, R_{19}, R_{20}, R_{21}, R_{22}, R_{23}: hydrogen

Z: phenyl or pyridine

B: formula (8) only in the case of $-NR_{25}R_{26}$

R_{25}, R_{26}: H or substituted alkyl

Reduction to Structure or Chemical Formulas

Therefore, there is no disclosure of species (e.g. by reduction to structural/chemical formulae) in addition to those reduced to practice.

Correlation between Structure and Function:

A correlation between structure and function, for the instantly claimed genus of compounds, is neither known in the art nor disclosed in the specification. Thus, it is not understood what unrepresented species will contain the instant activity.

III. ***Analysis of Fulfillment of Written Description Requirement:***

The structural/activity relationship (SAR) for binding and activity is elucidated upon analysis of IC_{50} data of multiple compounds with various types of structural modifications. These types of studies provide insight into the structural limitations that are required for activity, i.e., specific structural elements essential for the claimed activity. In the absence of such correlation, it is not possible to determine what structural modifications will allow for the preservation of the desired activity.

In conclusion, (i) substantial structural variation exists in the genus/subgenera embraced by claims 1-15; (ii) disclosure of species supporting genus is limited to compounds reduced to practice, which scope is not commensurate with the scope of genus/subgenera claimed; (iii) common structural attributes of the

genus/subgenera, combined with a correlation between structure and function, is neither disclosed in the instant application nor commonly known in the art. Thus, the specification fails to provide adequate written description for the genus of compounds claimed and does not reasonably convey to one skilled in the relevant art that the invention(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

9. Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The specification is enabling for the use of the compound that have adequate written description (see section 8). The specification is not enabling for the use of compounds not supported by the disclosure.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with the claims.

The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916) which postured the question: is the experimentation needed to practice the invention undue or unreasonable? That standard is still the one to be applied. *In re Wands*, 858 F.2d 731,737, 8USPQ2S 1400, 1404 (Fed. Cir. 1988). MPEP 2164.01(a) states "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue." The factors are applied below to the instant claims.

The breadth of the claims

Compounds not supported by the disclosure (see above section 8)

The nature of the invention

The compounds are disclosed to be anti-virals and antagonists against chemokine receptor CXCR4. An alternate utility is neither disclosed in the specification nor known in the art for this genus of compounds.

The state of the prior art/level of ordinary skill/level of predictability

The level of ordinary skill is high, but the level of predictability in the art is low. Since SAR studies are not available for the instantly claimed genus of compounds, it is not known what structural limitations are required for preservation of activity within the genus. In view of the low level or predictability one of ordinary skill would not know what structural modifications within the unrepresented genus (ie. unrepresented by the disclosure), if any, would lead to compounds that are active.

The amount of direction provided by the inventor/existence of working examples

Direction and working examples are limited to the genus of compounds that have adequate written description support (see section 8).

The quantity of experimentation needed to make or use the invention

It is not known which of the unrepresented compounds meet the structural requirements for activity. Thus, one of ordinary skill would not be enabled by the disclosure to make/use the claimed anti-virals. The amount of experimentation needed to practice the invention is undue. Further, absent an alternate utility, one of ordinary skill would not be enabled to use the compounds within the genus that are not adequately supported in the disclosure.

(Second Paragraph)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-10 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite various formula names for each formula described within the claim. It is unclear what the name of each formula actually is. For example, for variable W, it can be represented by formulae (10) and (11), but formulae (10) and (11) are also named [Formula 3] within the claims. Furthermore, later in the claim there is another [Formula 10] and [Formula 11] which are represented by (13), (15), and (7). It is unclear which formulae are referring to which substituents and variables within the claims. This occurs many times within the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

11. Claims 1-15 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Yamazaki et al (WO04/024697).

Many of the embodiments in the table of Yamazaki, pages 239-253 clearly anticipate the instant claims. Some of the examples that anticipate the instant claims are: 1-3, 7, 15-16, 19-31, 33, 35-36, 39-41, 43-87, 90-1110, etc.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1-4, 6-9, and 11-15 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 7,716,227, although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons. Claims 1-9 of U.S. Patent No. 7,716,227 are completely encompassed by the instant claims, in other words, the subgenus formed by claims 1-9 of U.S. Patent No. 7,716,227 anticipates the genus of the instant claims.

13. Claims 1-4, 6-9, and 11-15 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 18-32 and 49-65 of copending U.S. Patent application No. 11/704,860, although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons. Claims 18-32 and 49-65 of copending U.S. Patent application No. 11/704,860, are encompassed by the instant claims, in

other words, the subgenus formed by those claims anticipates the genus of the instant claims, and furthermore, there is significant overlap within the embodiments encompassed by the claims. This rejection is provisional because the claims have not yet been patented.

Conclusion

14. No claims are allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samantha Shterengarts whose telephone number is (571)270-5316. The examiner can normally be reached on Monday thru Thursday 9-6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Samantha L. Shterengarts/
Examiner, Art Unit 1626

/Kamal A Saeed/
Primary Examiner, Art Unit 1626